Standard Operation Procedures	SOP_003
Effective Date: 2024.06.05	**Public**

Lifecycle of scientific cross-cutting and sectoral guidance documents

Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls. Please note that this document becomes uncontrolled once printed. Make sure by always referring only to the Repository that you have the right version in use. Deviations from the provision of this document need to be recorded in the Exception Request Workflow. The procedure should be updated when there are changes in EFSA with respect to what is stated in the document (e.g. Relevant Standards, legislation, and documents, change in procedure, etc.). The person responsible for maintaining this procedure up to date is the Lead author with the support of the QM.

Process Responsibility	Process owners are accountable this procedure being adhered to within their respective or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document.

SCOPE AND OBJECTIVES

This SOP describes the steps of the lifecycle of EFSA's Scientific Committee, Scientific Panels and Units scientific guidance documents (cross-cutting and sectoral).
The steps concerning the lifecycle of guidance documents of the Pesticides Peer Review unit, the Pesticides Residues Team and Plant Protection Products and their Residues (PPR) Panel are out of the scope of this SOP as the development and the updating of risk assessment guidance documents are discussed by the Members of the Pesticides Steering Network as described in the mandate (M-2014-0228) and/or carried out under specific request by the European Commission.
Also, administrative guidance documents that could be considered as sectoral are out of the scope of this SOP, as well as Guidance documents addressing complex issues that span the sectors covered by different EU agencies require a multi-competence approach. For these, inter-institutional guidance documents are developed jointly by the concerned EU agencies. Their development is mostly triggered by requests from the European Commission. Inter-institutional guidance documents are not subject of this document.

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

- Definitions of EFSA Scientific Outputs and Supporting Publications
- EFSA Scientific Committee, 2015. Scientific Opinion: Guidance on the review, revision and development of EFSA's Cross-cutting Guidance Documents. EFSA Journal 2015; 13(4):4080, 11 pp. doi:10.2903/j.efsa.2015.4080
- EFSA Scientific Committee, 2014. Guidance on the structure and content of the EFSA scientific opinions and statements. EFSA Journal 2014;12(9) 3808, 10 pp. doi:10.2903/j.efsa.2014.3808
- EFSA Founding Regulation (No 178/2002) of 28 January 2002
- Regulation (EU) 1381/2019, the 'Transparency Regulation'
- SOP_006: Establishing, updating and closing WGs
- SOP_007 Risk Assessment of Generic mandates
- SOP_012_Risk Assessment of Applications
- SOP_13_Risk Assessment of Pesticides
- SOP_014_Publishing a scientific output in the EFSA Journal and Supporting Publications
- WIN_SOP003/02_Dissemination and capacity building activities for the implementation of EFSA CC GD's
- WIN_SOP00_71_Processing of public_consultation
- EFSA cross-cutting guidance lifecycle (EFSA 2018)
- EFSA Repository of documents catalogues (Overview of all EFSA Scientific Guidances)

ABBREVIATIONS AND DEFINITION

Cross-cutting guidance Document (CC GD)	Guidance document that is applicable to more than one panel, or that is of horizontal nature.
Catalogue of EFSA Scientific GDs	Excel file containing the titles of the most updated versions of the EFSA GDs (cross-cutting and sectoral) as well as the respective links to the EFSA website and other supporting information (e.g., DOIs, Scientific Unit responsible, etc.) Scoping document - Document to be prepared for any project in its envisioning phase

Case Management TOOL	APPIAN
DMS	Document Management System
EFSA	European Food Safety Authority
EPA	EFSA Process Architecture
Guidance document (GD)	The term covers both cross-cutting and sectoral guidance documents. Guidance documents of the Scientific Committee/Panel/Units explain the principles behind EFSA's procedures and approaches to scientific assessments. Some Guidance documents specify the information and data which applicants must provide when submitting applications for evaluation.
LA Unit	Legal Affairs Services Unit
RAL	Risk Assessment Logistics
Repository	EFSA Repository of Governance and Management Documents – the unique point of reference for legal acts, governance, management documents in force.
Review	The activity to indicate the screening of existing guidance documents in order to decide whether any revision is needed.
Revision	The activity to amend or update existing guidance documents.
QM	Team Quality Management Team
SMU	Subject Matter Unit
Sectoral guidance Document (SGD)	Guidance document specific to one Panel or Unit
SC	Scientific Committee
SOP	Standard Operating Procedure
SP	Scientific Panel
Tollgate	Quality check point during the risk assessment process
PROCEDURE	
Phase 1	**Identification of need**
Step 1	**1.0 Mechanisms for identifying topics for new GDs**
SC/SP/SMUs FDP	Sectoral guidance documents development is mostly triggered by requests from the European Commission or by the need identified within a specific Unit/Panel. In this latter case, go to step 1.4. For cross-cutting guidance only, the following steps (step 1.1, 1.2 and 1.3) apply: **1.1** The SMU coordinating the development of the cross-cutting guidance consults all units/panels and governance bodies by email to gather feedback for new GD development. Also, the Advisory Forum and the Stakeholder Forum may provide strategic input to future priorities for guidance development. The Scientific Committee,

	as the general coordinator for consistency of working procedures and harmonisation of working methodologies, plays an important role in identifying gaps and needs for cross-cutting guidance development based on its expertise, the presented information and analysis. This consultation is done before each panel renewal (i.e. every 5 years) or when deemed necessary. **1.2** After the collection of proposals, all topics are discussed in a dedicated SC plenary meeting. The result of the discussion is recorded in the plenary minutes. The outcome should identify the topics for which a need for a guidance is agreed by the SC. A preliminary prioritisation, according to the urgency of the need identified for guidance development, is also proposed. DG Sante is consulted to indicate priorities and to take note of the proposed topics for guidance development. **1.3** Prioritisation criteria for cross-cutting guidance development include, but are not limited to: • the degree of impact of the proposed guidance on the scientific assessments; • improving the consistency in the way scientific assessment is carried out by the EFSA Panels; • the number of EFSA Panels for which the guidance is relevant; • Relevance indicated by consultation with risk managers (e.g. DG Sante). • View of the EFSA preparedness council (see here EFSA DMF) **1.4** Once the need for guidance document(s) has been agreed by the SC/Panel, this is included in the yearly work programme. The work-programme can be revised, if and when needed, to reconsider priorities.
Macro-phase 2	**Development**
Step 2	**2.0 Development of cross-cutting / sectoral GDs**
FDP	**Mandate intake** (Please refer to the WIN_SOP007/02_Mandate Dialogue and Scientific Workforce planning)
	In case of EC mandate for cross cutting/sectoral guidance development, please refer to SOP 7 on generic mandates. **For the sectoral guidance development, steps 2.3 to 2.12 below apply.**
SC/SP/SMUs	In case of cross-cutting/sectoral guidance development as **self-task/internal mandate**, the following steps apply: **2.1** a self-task mandate is drafted, usually with the assistance of some Scientific Committee/panel members. For mandate dialogue and scientific workforce planning the relevant WIN 07_02 applies.

	2.2 It is decided if the mandate should be carried out by an existing WG or by a new WG (please refer to SOP 6 for establishment/updating of a WG). For cross-cutting guidance documents, it is important that the expertise gathered in the WG covers the areas of all Panels that will be concerned by the guidance, and that throughout the development phase, regular updates on the progress made are provided to these Panels by their Chairs to ensure that the final deliverable suits their needs and adequately supports their scientific assessments. **2.3** In developing the guidance, the WG could consider the need for case studies illustrating how it could be applied in the different areas concerned. A piloting phase to check the applicability of the guidance and to identify possible issue could be considered. **2.4** The draft guidance is subjected to a public or/and targeted consultation to collect input from Panels and staff, and external stakeholders including EU agencies and MSs on its clarity, completeness and applicability. The version tabled to Scientific Panel/SC plenary meeting for endorsement for consultation is considered to have passed **tollgate 2 as described in SOP_007_ Risk assessment of Generic Mandates (tollgate 1 does not exist for guidance as no protocol is developed).** **2.5** The RAL assistant or responsible SO(s) reports the date of passing **Tollgate #2** in the Case Management Tool. **2.6** After the public consultation, comments are addressed by the relevant WG or EFSA SO(s) and the draft is finalised. **2.7** The draft is then submitted to the EFSA Scientific Committee/Scientific Panels for adoption. The version submitted for adoption is considered to have passed **tollgate 3 as described in SOP_007_ Risk assessment of Generic Mandates.** **2.8** The RAL assistant or responsible SO(s) reports the date of passing Tollgate #3 in the Case Management Tool.
Phase 3	**Implementation**
Step 3	**3.0 Implementation**
SC/SP/SMUs	**3.1** For each Guidance document (cross cutting and sectoral), an implementation plan is agreed with EFSA management, where needed in consultation with the EC . A transition period is agreed to give time to EFSA Units and panels to fully align with the requirements of the new guidance. Unless specified otherwise in the implementation plan, a guidance document has to be applied to all new risk assessment projects that start 6 months after its publication (deviation can occur if duly justified). In cases where the new cross cutting guidance is very complex and/or has a high impact on risk assessment procedures, the implementation plan can foresee a gradual application of the guidance by the Scientific Panels over a certain period, but not

	exceeding one year. This decision is recorded in the minutes of the plenary meeting and in the implementation plan where the guidance is adopted. **3.2** Where appropriate, cross-cutting guidance documents should be incorporated or referenced to the extent possible in sectoral guidance documents. **3.3** EFSA Panels and Units must ensure that their existing approaches are in line with the requirements of the new guidance document, unless duly justified
Step 4	**4.0 Dissemination and Capacity building for guidance documents**
SC/SP/SMUs	**4.1** After its adoption by the SC/SP or endorsement by EFSA, as part of the normal roll out procedure, the guidance document is published in the EFSA Journal **4.2** The guidance document is included in the EFSA repository on EFSA's document management system. All the steps of the dissemination and capacity building are described in the WIN/SOP3/02.
Step 5	**5.0 Post-adoption monitoring of the implementation of guidance documents**
SC/SP/SMUs	**5.1** In accordance with its policy on quality and as part of its quality management system, EFSA monitors, with a range of different activities and tools, qualitative and/or quantitative (e.g., surveys and citation analysis), the implementation of guidance documents with the aim of identifying any issue regarding their use. **5.2** Regular feedback on the impact of applying the guidance should be collected and lessons learnt during the implementation are gathered in this process (e.g. a tailored survey can be launched to EFSA panels and experts). Results are analysed as part of the general feedback used to improve the implementation activities and to inform the review process. **5.3** The conclusions are compiled in a technical report and should be the basis for the next actions on the GD in question.
Phase 4	**Review & Revision**
Step 6	**6.0 Review of guidance documents**
SC/SP/SMUs	**6.1** At the beginning of the fifth year of the SC/SP mandate, or at any time a need is identified (e.g., an urgent scientific need/request or annual planning), the SMU that developed the guidance places the possible review of guidance documents belonging to their remit on the agenda of the SC/SP plenary meeting. **6.2** The SC/SP/SMUs could base their review on the following criteria: a. which guidance documents were used; b. which guidance documents were not used and why not;

	c. any problems or difficulties identified during the use of guidance documents. **6.3** The outcome of the review will result in one of the following decisions for each of the guidance documents: a. guidance document is to be kept (no further action needed); b. guidance document is to be archived as obsolete (SMU secretariat to send e-mail to repository mailbox to inform repository manager of request to archive the guidance document. The EFSA Journal should also be informed so that the obsolete guidance document is labelled as such in the EFSA Journal and therefore no longer applicable); c. guidance document needs revision. **6.4** Possible reasons for the need to revise a guidance document may be: a) New relevant, reliable and consistent scientific information/insight in hazard and/or exposure assessments has become available (e.g., concerning assumptions, exposure routes, identified group of sensitive individuals, methodologies) b. New regulation or new legal instruments have been published which have an impact on one or several EFSA scientific panels. c. A request from the Commission or a Member State forrevision of guidance document(s) has been received. d. Mistakes or ambiguity have been identified that directly influence the outcome of the scientific assessment. e. The identification of different interpretations of the guidance by different Panels/Stakeholders due to ambiguity in existing guidance documents. f. A need to reflect changes in target audience or application area. **6.5** The decision concerning the outcome of the review will be recorded in the SC/SP or SMU meeting minutes. In the case of cross-cutting guidance documents, the outcome of the review should be also communicated to the relevant panels and units.
Step 7	**7.0 Revision of guidance documents**
SC/SP/SMUs	**7.1** If the need for a revision/update has been identified during the review process, the SC/SP/SMUs should carry out a prioritisation exercise leading to a suggested timing of the foreseen revisions. For possible prioritisation criteria, see points 1.3. For each guidance to be revised/updated, a new question number needs to be created in the Open EFSA linked to an existing or new mandate. This allows a unique output number to be generated for the revised/updated guidance at the time of publication. **7.2** The SC/SP/SMUs record the decision on the prioritisation in the relevant meeting minutes.

Step 8	**8.0 Communication on revised guidance documents**
	In case of revised guidance documents, steps 4, 5 and 7 apply.
	Following SOPs in the process: SOP 014 (Publishing a scientific output in the EFSA Journal)